Complete Summary

GUIDELINE TITLE

Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology.

BIBLIOGRAPHIC SOURCE(S)

Rizzo JD, Lichtin AE, Woolf SH, Seidenfeld J, Bennett CL, Cella D, Djulbegovic B, Goode MJ, Jakubowski AA, Lee SJ, Miller CB, Rarick MU, Regan DH, Browman GP, Gordon MS. Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. Blood 2002 Oct 1;100(7):2303-20. PubMed

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COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Treatment-associated anemia (caused by chemotherapy or radiation therapy)
- Cancer-associated anemia
- Anemia associated with bone marrow failure (e.g., myelodysplasia and aplastic anemia)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Hematology
Oncology
Radiation Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To delineate, according to the best available evidence, which patients should receive epoetin, the appropriate dosages and routes of administration, and the duration of treatment

TARGET POPULATION

Patients with anemia caused by chemotherapy or radiation therapy, anemia associated with cancer, and anemia associated with bone marrow failure (myelodysplasia and aplastic anemia)

INTERVENTIONS AND PRACTICES CONSIDERED

1. History and physical to identify causes of anemia, including drug exposure history; peripheral blood smear; iron, folate, and B12 deficiency; assessment for occult blood loss; Coomb´s testing; and endogenous erythropoietin levels.
2. Epoetin treatment with periodic monitoring of hemoglobin levels for response
3. Red blood cell transfusion alone or as supplement to epoetin treatment
4. Baseline and periodic monitoring of iron, total iron-binding capacity, transferrin saturation, or ferritin levels

MAJOR OUTCOMES CONSIDERED

Primary outcomes

- Requirements for transfused red blood cells (RBCs)
- Changes in hemoglobin or hematocrit concentration

Secondary outcome

- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) submitted a formal proposal to the Agency for Healthcare Research and Quality (AHRQ) for an evidence-based practice center review on the use of epoetin in cancer patients. The Blue Cross and Blue Shield Association´s Technology Evaluation Center (TEC) staff searched MEDLINE, Cancerlit, and Embase databases for all relevant articles published since 1985. The TEC staff supplemented the above strategy by searching issues of Current Contents on Diskette and Medscape Oncology through October 30, 1999, to identify recently published articles that had not yet been indexed by the online databases. The reviewers also examined abstracts presented at the 1999 meeting of the American Society of Clinical Oncology, bibliographic information and reprints of clinical studies provided by Ortho Biotech, Inc, and reference lists from relevant review articles, editorials, and letters published after 1994. Subsequently, the panel also reviewed emerging evidence on a new agent, darbepoetin, and kept abreast of other important emerging evidence that is cited in this document.

Inclusion criteria

Admissible evidence included controlled trials (randomized and nonrandomized) that compared the outcomes of managing anemia with and without the use of epoetin. All trials that met study selection criteria compared epoetin plus red blood cell transfusion as necessary with red blood cell transfusion alone. Studies had to include at least 10 similarly treated evaluable patients in each arm, relevant strata, and relevant epoetin dose level. Studies that used nonrandomized concurrent or historical controls were included only if the reviewers were satisfied that patients in the treatment and control groups were comparable at baseline and that obvious selection bias was absent; however, it is acknowledged that the nature of such designs cannot completely protect against such biases. Two reviewers independently conducted each step in the review process. Disagreements were resolved by consensus.

The guideline panel relied mainly on the evidence review performed by TEC staff in developing the guideline. However, the panel, with acknowledgment of their design limitations, also included large community studies excluded by TEC staff because of methodological concerns. A summary and critical appraisal of the studies reviewed for this guideline can be found in Tables 2-5 (chemotherapy-induced anemia) and Appendix B of the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Anemia due primarily to cancer therapy

22 controlled trials met the selection criteria

Anemia due primarily to malignant disease

6 controlled trials met the inclusion criteria

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Type of evidence

Level I: Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power).

Level II: Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or -negative errors (low power).

Level III: Evidence obtained from well-designed, quasi-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series.

Level IV: Evidence from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies.

Level V: Evidence from case reports and clinical examples.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis

To supplement the systematic review, the team conducted a meta-analysis of the effect of epoetin on the odds of transfusion in patients with anemia or at risk of anemia due primarily to cancer therapy. A random effects model was used to combine results of the 14 randomized controlled trials that reported numbers of patients transfused. The odds ratio expresses the relative likelihood that epoetin-treated patients will be transfused compared to the likelihood for control patients.

Sensitivity analysis was performed to compare results of higher quality trials to lesser quality trials. A trial was classified as higher quality when it was randomized and double-blinded and met the team's criteria to limit subjects excluded from the analysis of results. It required that less than 10 percent of subjects within each study arm were excluded from the analysis, and that the ratio of exclusions between arms was less than a 2:1 ratio; or, alternatively, that results were reported as an intention to treat analysis.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The panel considered it essential to use a systematic review of the evidence as its foundation for making recommendations. When evidence was lacking, the panel determined that it was appropriate to reach conclusions based on expert opinion as long as it was acknowledged explicitly. The panel determined that consensus would be reached by majority vote.

The panel met on several occasions. After developing procedures and reviewing the evidence as presented by the Technology Evaluation Center (TEC) report, draft recommendations were prepared and discussed in a face-to-face meeting before the completion of a full draft report. All panel members reviewed all iterations of the guideline, contributing feedback to the levels of evidence and the systematic grading of the data supporting the recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of recommendations

Grade A: There is evidence of type I or consistent findings from multiple studies of type II, III, or IV.

Grade B: There is evidence of type II, III, or IV, and findings are generally consistent.

Grade C: There is evidence of type II, III, or IV, but findings are inconsistent.

Grade D: There is little or no systematic empirical evidence.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All panel members reviewed all iterations of the guideline, contributing feedback to the levels of evidence and the systematic grading of the data supporting the recommendations.

Independent review from three external experts was obtained. The final content of the guidelines and the manuscript were reviewed and approved by the American Society of Clinical Oncology (ASCO) Health Services Research Committee and Board of Directors, and the American Society of Hematology (ASH) Executive Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I-V) and grades of recommendation (A-D) are given at the end of the "Major Recommendations" field.

General Recommendation

As in any medical situation, it is essential to give consideration to other correctable causes of anemia before proceeding to therapy with stimulants of erythropoiesis. Therefore, it is advisable to conduct an appropriate history and physical, and to consider relevant diagnostic testing aimed at identifying causes of anemia aside from chemotherapy or underlying hematopoietic malignancy. At a minimum, one should take a thorough drug exposure history; carefully review the peripheral blood smear (and in some cases the bone marrow); consider iron, folate, or B12 deficiency where indicated; and assess for occult blood loss. Coombs testing may be appropriate for patients with chronic lymphocytic leukemia; endogenous erythropoietin levels may predict response in patients with myelodysplasia.

Chemotherapy-Induced Anemia

Recommendation: The use of epoetin is recommended as a treatment option for patients with chemotherapy-associated anemia and a hemoglobin concentration that has declined to a level $\leq$10 g/dL. Red blood cell transfusion is also a treatment option depending upon the severity of anemia or clinical circumstances.

Level of evidence: II (several small and one larger [N = 375] placebo-controlled, randomized trials and nonblinded trials with generally consistent results favoring the use of epoetin).

Grade of recommendation: B

Recommendation: For patients with declining hemoglobin levels but less severe anemia (those with hemoglobin concentration < 12 g/dL but who never have fallen below 10 g/dL), the decision of whether to use epoetin immediately or to wait until hemoglobin levels fall closer to 10 g/dL should be determined by clinical

circumstances. Red blood cell transfusion is also a therapeutic option when warranted by severe clinical conditions.

Level of evidence: II (several small [N < 100], randomized and nonrandomized, mostly nonblind studies consistently favoring epoetin but with inconsistent statistical significance for reported outcomes across the studies).

Grade of recommendation: C

Recommendation: The recommendations are based on evidence from trials in which epoetin was administered subcutaneously thrice weekly. The recommended starting dose is 150 U/kg thrice weekly for a minimum of 4 weeks, with consideration given for dose escalation to 300 U/kg thrice weekly for an additional 4-8 weeks in those who do not respond to the initial dose. Although supported by less strong evidence, an alternative weekly dosing regimen (40,000 U/week), based on common clinical practice, can be considered. Dose escalation of weekly regimens should be under similar circumstances to thrice weekly regimens.

Level of evidence: II (19 comparative, controlled trials involving a total of 1618 patients, of which 15 trials were randomized and 6 were either blind or placebo-controlled. Epoetin was administered 3 times weekly in the treatment arm for all controlled trials reviewed except one, where it was administered daily.)

Grade of recommendation: B

Recommendation: Continuing epoetin treatment beyond 6-8 weeks in the absence of response (e.g., < 1-2 g/dL rise in hemoglobin level), assuming appropriate dose increase has been attempted in nonresponders, does not appear to be beneficial. Patients who do not respond should be investigated for underlying tumor progression or iron deficiency. As with other failed individual therapeutic trials, consideration should be given to discontinuing the medication.

Level of evidence: N/A (expert opinion based on indirect evidence and biological inference).

Grade of recommendation: Panel consensus.

Recommendation: Hemoglobin levels can be raised to (or near) a concentration of 12 g/dL, at which time the dosage of epoetin should be titrated to maintain that level or restarted when the level falls to near 10 g/dL. Insufficient evidence to date supports the "normalization" of hemoglobin levels to above 12 g/dL.

Level of evidence: N/A (expert opinion based on indirect evidence and biological inference).

Grade of recommendation: Panel consensus.

Recommendation: Baseline and periodic monitoring of iron, total iron-binding capacity (TIBC), transferrin saturation, or ferritin levels and instituting iron repletion when indicated may be valuable in limiting the need for epoetin, maximizing symptomatic improvement for patients, and determining the reason

for failure to respond adequately to epoetin. There is inadequate evidence to specify the optimal timing, periodicity, or testing regimen for such monitoring.

Level of evidence: N/A (expert opinion based on indirect evidence and biological inference).

Grade of recommendation: Panel consensus.

Myelodysplasia, Multiple Myeloma, Non-Hodgkin´s Lymphoma, and Chronic Lymphocytic Leukemia (anemia primarily related to hematologic malignancy)

Recommendation: There is evidence from one well-designed, placebo-controlled randomized trial that supports the use of epoetin in patients with anemia associated with low-risk myelodysplasia, but there are no published high-quality studies to support its use in anemic myeloma, non-Hodgkin´s lymphoma, or chronic lymphocytic leukemia patients in the absence of chemotherapy. Treatment with epoetin for myeloma, non-Hodgkin´s lymphoma, or chronic lymphocytic leukemia patients experiencing chemotherapy-associated anemia should follow the recommendations outlined in the previous section.

Level of evidence: II (one placebo-controlled randomized trial in myelodysplasia involving 87 patients and using a credible clinical outcome measure; five randomized trials with important design or reporting flaws for patients with lymphatic malignancy and/or myeloma not necessarily receiving chemotherapy at enrollment).

Grade of recommendation: B

Recommendation: Physicians caring for patients with myeloma, non-Hodgkin´s lymphoma, or chronic lymphocytic leukemia are advised to begin treatment with chemotherapy and/or corticosteroids and observe the hematologic outcomes achieved solely through tumor reduction before considering epoetin. If a rise in hemoglobin level is not observed following chemotherapy, epoetin should be used in accordance with the criteria outlined above for chemotherapy-associated anemia if clinically indicated. Blood transfusion is also a therapeutic option.

Level of evidence: IV (indirect evidence generalized from studies involving other patient populations).

Grade of recommendation: C

Definitions:

Levels of Evidence and Grade of Recommendations

Type of evidence

Level I: Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power).

Level II: Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or -negative errors (low power).

Level III: Evidence obtained from well-designed, quasi-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series.

Level IV: Evidence from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies.

Level V: Evidence from case reports and clinical examples.

Grade of recommendations

Grade A: There is evidence of type I or consistent findings from multiple studies of type II, III, or IV.

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Grade C: There is evidence of type II, III, or IV, but findings are inconsistent.

Grade D: There is little or no systematic empirical evidence.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (See Major Recommendations).

The review identified 22 controlled trials meeting the selection criteria with a total enrollment of 1,927 patients with chemotherapy-induced anemia. Eighteen trials were randomized, and seven of these 18 trials were placebo-controlled and double-blinded.

An additional six randomized controlled trials with a total enrollment of 693 patients were found on anemia due primarily to malignant disease.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Chemotherapy-induced anemia

For patients with anemia resulting primarily from cancer therapy, epoetin reduces the odds of transfusion. The overall number-needed-to-treat (NNT) is 4.4 (95% confidence interval [CI], 3.6 to 6.1), which suggests four to five patients must be treated to spare one patient from transfusion. Sensitivity analysis found a smaller magnitude of risk reduction for double-blinded compared with unblinded studies. A large, double-blinded randomized trial, not yet published, found improvement in quality-of-life scores with epoetin. Assessment of the study methodology and clinical significance of the findings awaits publication of the full report. The most robust evidence that epoetin improves outcomes is from trials in patient groups with baseline hemoglobin (Hb) at or below 10 g/dL. The evidence is not adequate to determine whether outcomes are superior when epoetin treatment is initiated at higher hemoglobin thresholds.

Anemia primarily related to hematologic malignancy

Anemia primarily a result of malignancy included patients with multiple myeloma, non-Hodgkin´s lymphoma, chronic lymphocytic leukemia, and myelodysplastic syndromes. Epoetin increases Hb levels and achieves statistically significant hematologic response rates in these patients. The evidence on transfusion outcomes is sparse but suggests a favorable effect of epoetin. Hematologic response rates appear to be lower for patients with myelodysplastic syndrome; higher doses of epoetin may be necessary to achieve response.

POTENTIAL HARMS

- Hypertension and thromboembolic events are known adverse effects of epoetin, but are generally manageable.
- A substantial proportion of patients that receive epoetin report adverse events. Of the 10 studies reporting "any adverse event" among the 1155 patients, the rate was 46% among the controls and 56% among the epoetin-treated groups. These complications, however, are often reasonably ascribable to concurrent treatments or to the underlying disease. Most of the trials examined for this guideline evaluated relatively few patients. Trials powered to detect specified differences in main outcomes may not have sufficient power to detect adverse events that are less frequent. With relatively few patients in each study arm, differences in adverse events in these trials are unlikely to achieve statistical significance.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The American Society of Hematology and the American Society of Clinical Oncology acknowledge that guidelines cannot always account for individual variations among patients. Guidelines are not intended to supplant physician judgment with respect to particular patients or special clinical situations and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same results. Accordingly, the American Society of Hematology and the American Society of Clinical Oncology consider adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the

physician in light of each patient´s individual circumstances. In addition, these guidelines describe administration of therapies in clinical practice; they cannot be assumed to apply to interventions performed in the context of clinical trials, given that clinical studies are designed to test innovative and novel therapies in a clinical situation where better therapy is needed.

- Many studies used quality-of-life (QOL) instruments that have only recently been introduced. Since the experience with these instruments is limited, research defining minimum clinically meaningful changes in quality-of-life scores is ongoing. In particular, psychometric research is underway to quantify the clinical impact associated with changes in the quality-of-life measured by one popular instrument, the Functional Assessment of Cancer Therapy General version (FACT-G). Because the trials on which these conclusions are based are only of fair quality regarding quality-of-life outcomes (due to limitations in reporting and conduct of the investigations), the probability of false-positive and false-negative results cannot be assumed to be low (level II evidence; see Table 6 of the original guideline document). In making recommendations for use of epoetin, the evidence for improvements in hemoglobin and transfusion outcomes was considerably stronger than that for quality-of-life outcomes. Replication of quality-of-life improvements that are demonstrated to be clinically meaningful in other well-designed clinical trials would improve the strength of evidence and further support this recommendation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rizzo JD, Lichtin AE, Woolf SH, Seidenfeld J, Bennett CL, Cella D, Djulbegovic B, Goode MJ, Jakubowski AA, Lee SJ, Miller CB, Rarick MU, Regan DH, Browman GP, Gordon MS. Use of epoetin in patients with cancer: evidence-based clinical

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Apr 18

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society
American Society of Hematology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology
American Society of Hematology

GUIDELINE COMMITTEE

Epoetin Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Potential conflicts of interest were handled through full disclosure and according to the policies of American Society of Hematology (ASH) and American Society of Clinical Oncology (ASCO). As part of the conflicts of interest consideration, the relationship of Technology Evaluation Center (TEC) to the Blue Cross and Blue Shield Association was addressed.

ASCO/ASH Epoetin Expert Panel

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Consultant within the last 2 years for Amgen; received research funding from Amgen; received honoraria directly in excess of $2000 per year or $5000 over a 3-year period from Amgen; a member on the Board of Directors or Advisory Committee of Amgen.

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No conflicts noted.

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No conflicts noted.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology.

Electronic copies: Also available in PDF format from the American Society of Hematology (ASH) Web site.

Print copies: Available from American Society of Clinical Oncology (ASCO), Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Uses of Epoetin for Anemia in Oncology. Rockville, MD: Agency for Healthcare Research and Quality. 2001 Mar. (Evidence Report/Technology Assessment; no. 30).

Electronic copies and further information regarding the availability of print copies is available from the Agency for Healthcare Research and Quality (AHRQ) Web site.

PATIENT RESOURCES

A Patient Guide titled "Epoetin treatment. Information for people living with cancer" is available from the American Society for Clinical Oncology's - People Living With Cancer Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 16, 2003. The information was verified by the guideline developer on June 25, 2003.

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